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TO:

Name: Mail Stop Appeal Brief--Patents
Art Unit 3764/Examiner D. DeMille

Firm: U.S. Patent & Trademark Office

Fax No.: 703-872-9306

Subject: U.S. Patent Application No. 08/354,450
Gary K. Michelson
Filed: December 12, 1994
DEVICE FOR ARTHROSCOPIC MENISCAL
REPAIR

Attorney Docket No. 101.0023-04000

Customer No. 22882

Confirmation No.: 3041

FROM:

Name: Todd M. Martin

Phone No.: 310-286-9800

No. of Pages (including this): 19

Date: February 1, 2006

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Message:

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that the attached Transmittal Form (in duplicate) and Supplemental Reply Brief with Exhibit A are being facsimile transmitted to the U.S. Patent and Trademark Office on February 1, 2006.



Todd M. Martin

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary K. Michelson

Serial No: 08/354,450

Filed: December 12, 1994

For: DEVICE FOR ARTHROSCOPIC
MENISCAL REPAIR

Confirmation No.: 3041

Art Unit: 3764

Examiner: D. DeMille

Mail Stop Appeal Brief--Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith is a Supplemental Reply Brief with Exhibit A in response to the Supplemental Examiner's Answer dated December 1, 2005 in the above-identified application.

- ☒ Applicant claims small entity status under 37 C.F.R. §§ 1.9 and 1.27.
- ☒ No additional fee is required.
- ☐ Applicant hereby requests a ***-month extension of time to respond to the above action.
- ☐ The total amount of \$*** to cover the above fees is to be charged to Deposit Account No. 50-1066.
- ☒ The Commissioner is hereby authorized to charge any deficiencies of fees associated with this communication or credit any overpayment to Deposit Account No. 50-1066. **A copy of this sheet is enclosed.**
 - ☒ Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
 - ☒ Any patent application processing fees under 37 C.F.R. § 1.17

Respectfully submitted,
MARTIN & FERRARO, LLP

Date: February 1, 2006

By: 

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PATENT
Attorney Docket No. 101.0023-04000
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Gary K. Michelson

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Examiner: D. DeMille

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- ☒ Any patent application processing fees under 37 C.F.R. § 1.17

Respectfully submitted,
MARTIN & FERRARO, LLP

Date: February 1, 2006

By: 

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PATENT
Attorney Docket No. 101.0023-04000
Customer No. 22882

APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)
Gary Karlin Michelson, M.D.)
Serial No.: 08/354,450) Group Art Unit: 3764
Filed: December 12, 1994) Examiner: D. DeMille
For: DEVICE FOR ARTHROSCOPIC)
MENISCAL REPAIR)

Mail Stop APPEAL BRIEF-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL REPLY BRIEF

Appellant submits the following reply to the Supplemental Examiner's Answer dated December 1, 2005 (the "Supplemental Examiner's Answer"). The following remarks are submitted for consideration by the Board of Patent Appeals and Interferences.

I. Status of Petition under 37 C.F.R. § 1.181(a).

On September 1, 2005, Appellant submitted a Petition under 37 C.F.R. § 1.181(a) to have a Corrected Examiner's Answer mailed designating several rejections as new grounds of rejection. As of the date of this Brief, the Petition is still pending before the Director of Technology Center 3700.

II. Remarks in response to the Supplemental Examiner's Answer.

Appellant replies to the Supplemental Examiner's Answer in the order that the objections and rejections were presented in the Supplemental Examiner's Answer using the section/sub-section numbering scheme applied in the Reply Brief filed September 1, 2005 (the "September 2005 Reply Brief") and referred to by the Examiner in the Supplemental Examiner's Answer. The section/sub-section referred to in the body of each heading correspond to the section/sub-section in the September 2005 Reply Brief unless otherwise indicated.

Supplemental Reply Brief 2-1-06.doc

A. Section I, sub-section A(3) of the September 2005 Reply Brief.

Appellant noted in the paragraph bridging pages 13 and 14 of the Appeal Brief dated April 20, 2005 (the "April 2005 Appeal Brief") that the Examiner had not provided any rationale for the rejection under 35 U.S.C. § 112, first paragraph specific to method claims 273-292. The Examiner acknowledged Appellant's observation concerning the lack of rationale specific to claims 273-292, but still failed to provide any rationale specific to these claims in the Examiner's Answer. (See Examiner's Answer, page 14, paragraph 4).

In the September 2005 Reply Brief, Appellant noted that the Examiner had not provided any basis or explanation as to what subject matter was considered to be new matter or not supported by the specification relative to the Examiner's new matter objection under 35 U.S.C. § 132 and rejections under 35 U.S.C. § 112, first and second paragraphs of method claims 273-292. (September 2005 Reply Brief, paragraph bridging pages 2 and 3). The Examiner acknowledged Appellant's observation concerning the lack of rationale specific to claims 273-292, but still has not provided any rationale specific to these claims in the Supplemental Examiner's Answer. (See Supplemental Examiner's Answer, page 3, paragraph 1). The Examiner states that "[i]t is believed that the new language to the claims including the method claims raises questions if the claims are supported by the original disclosure." (Supplemental Examiner's Answer, page 3, paragraph 1). This statement does not indicate what language of claims 273-292 is alleged to "raise questions" as to whether the claims are supported. Appellant's position has been and continues to be that claims 273-292 are fully supported and do not raise issues of new matter or lack of support.

Appellant has now twice pointed out that the objection under 35 U.S.C. § 132 and the rejections under 35 U.S.C. § 112, first and second paragraphs specific to claims 273-292 lack an explanation or rationale. As the Examiner has consistently failed to provide an explanation and support of his rejections of claims 273-292, Appellant respectfully requests that the objection under 35 U.S.C. § 132 and the rejections under 35 U.S.C. § 112, first and second paragraphs of claims 273-292 be withdrawn.

For the Examiner's remarks pertaining to independent claim 293, Appellant submits that the remarks contained in the April 2005 Appeal Brief adequately state Appellant's position on the Examiner's objection under 35 U.S.C. § 132 and rejections under 35 U.S.C. § 112, first and second paragraphs in view of the Examiner's Answer and Supplemental Examiner's Answer. (See April 2005 Appeal Brief, Section I, sub-section F, pages 12 and 13; Section II, page 13; and Section III, sub-section G, page 17, the remarks of which are hereby incorporated by reference herein).

B. Section II, sub-section E(ii) of the September 2005 Reply Brief.

For the Examiner's remarks pertaining to claim 145, the Examiner states that he "quoted the claim word for word" on page 5 of the Examiner's Answer, so that "[i]t is not clear how much weight can be given" to Appellant's argument. Appellant's remarks in the September 2005 Reply Brief concerning claim 145 relate to the Examiner's remarks on page 13 of the Examiner's Answer, where the Examiner states that "the limitation that a second portion of the bottom of the flexible member forms an included angle relative to the mid-longitudinal axis of the shaft is greater than 90 degrees in claim 145 is not contingent on when the flexible member is in contact with tissue." (Examiner's Answer, page 13, paragraph 2 (emphasis added)). Accordingly, the Examiner's remarks on pages 5 and 13 of the Examiner's Answer are inconsistent with each other.

In the Examiner's Answer, the Examiner states that the angular relationship is "a positive structural limitation of the device before use." (Examiner's Answer, page 13, paragraph 2). The Examiner states in the Supplemental Examiner's Answer that "[t]here is no temporal limitation of the recited language and therefore one would have to assume that it is a positive limitation." (Supplemental Examiner's Answer, paragraph bridging pages 3 and 4). Appellant respectfully disagrees with the Examiner's contentions. There is not any language in claim 145 that states that the angular relationship must exist "before use." Claim 145 states that the flexible member "forms an included angle relative to the mid-longitudinal axis." This relationship is clearly illustrated in Fig. 7 of Appellant's drawings. Accordingly, Appellant submits that claim 145 is fully supported by Appellant's disclosure.

C. Section II, sub-section K of the September 2005 Reply Brief.

Appellant respectfully submits that the Examiner's remarks with respect to the number of claims in this application are misplaced and baseless. The Examiner falsely contends, *inter alia*, that "appellant has overwhelmed the examiner in hopes of at least one claim will slip through." (Supplemental Examiner's Answer, page 4, paragraph 1). Appellant takes great exception to the Examiner's imputed motive for the number of claims in this case. Appellant has full faith in the Examiner's competency and expects nothing to "slip through." Appellant's only hope is to receive a fair examination of the claims.

The present application has an earliest claim to priority of December 5, 1988. Any continuation application filed off the present application would have a significantly shorter patent term, much of which would be consumed by normal prosecution. The present application was filed before the GATT provisions took effect and represents Appellant's only opportunity to have claims issue to the present invention with any meaningful patent term. As permitted by the provisions in the MPEP and the Code of Federal Regulations, Appellant submitted claims of varying scope to define and cover various embodiments of Appellant's invention. Of the 270 pending claims, 10 are independent claims and the rest are dependent claims from each of the Independent claims. Appellant further deems it necessary to have a variety of independent claims in view of the Examiner's unduly narrow interpretation of the specification. Appellant respectfully submits that the Examiner should not impugn Appellant's right to obtain the maximum claim protection Appellant is entitled to have for the present invention.

Appellant recognizes the time constraints Examiners endure in examining cases with more than 20 claims. However, Appellant should not be punished as result of the present system of examination procedures within the United States Patent & Trademark Office. Appellant paid considerable extra claims fees to obtain an examination of all of the claims.

The Examiner appears to contend that the angular relationships defined in claims 177 and 178 include language that is not supported under 35 U.S.C. § 112, first paragraph. Appellant respectfully traverses the Examiner's contention. Independent claim 176 recites a flexible member having an outer perimeter that is flexible relative to

the shaft "when said rivet is inserted into the tissue." Claims 177 and 178 define the outer perimeter being moveable relative to the shaft to form the angular relationships, examples of which are shown in Fig. 7. Accordingly, Appellant submits that the Examiner's rejections of claims 177 and 178 under 35 U.S.C. § 112, first and second paragraphs as not being supported have been overcome. Appellant notes that the Examiner still has not provided any specific explanation as to why claims 179-182, 186-210, 242-244, and 248-292 are rejected under 35 U.S.C. § 112, second paragraph, despite having three opportunities to do so. The Examiner's remarks that "[a] review of the above claims will reveal whether or not these claims contain the language the examiner is referring to" (Supplemental Examiner's Answer, page 4, paragraph 1) appear to indicate that the Examiner is expecting the Board to perform an initial examination of the claims rather than only review the Examiner's holding. Appellant respectfully submits that this is an improper use of the appeals process.

D. Section II, sub-section L of the September 2005 Reply Brief.

The Examiner contends that because the Warren device is made of the same material, has the same configuration, and a thickness of 0.069 inches, then this should allow the Warren device to flex in a manner that comes within the scope of Appellant's claimed invention. (Supplemental Examiner's Answer, page 4, paragraph 2). Appellant respectfully disagrees with the Examiner's contention. The Warren fastener is not configured in the same manner as the rivet of Appellant's claimed invention. The Warren fastener is structurally configured to withstand repeated blows due to the relative thickness of the head compared to the shaft walls, and the presence of fillet 161. Appellant respectfully submits that the Examiner has not taken into account the entire teaching of Warren in formulating the 35 U.S.C. § 103(a) rejections.

The Examiner further contends that Appellant's device "is intended to withstand repeated blows." The rivet of the present invention is configured to be pushed into position with a driver 130 having a face 135 that supports the flexible member. (See Specification, page 7, paragraph 3; and Fig. 5). The Warren fastener is repeatedly hit into position. The fastener of Warren is structurally incapable of flexing to the degree required by Appellant's claims. Appellant respectfully submits that the Examiner's attempt to modify the rivet of Warren to be flexible to the extent recited in Appellant's

claims goes beyond and contravenes the teachings of Warren.

III. Examiner's remarks pertaining to Appellant's Petition under 37 C.F.R. § 1.181(a).

The Examiner's remarks on pages 5 and 6 of the Supplemental Examiner's Answer relate to Appellant's Petition under 37 C.F.R. § 1.181(a) filed concurrently with the September 2005 Reply Brief. The undersigned telephoned the Examiner on December 8, 2005 to ascertain whether the Examiner's remarks in the Supplemental Examiner's Answer constituted a denial of Appellant's Petition. The Examiner indicated that the remarks in the Supplemental Examiner's Answer were not to be taken as a decision on Appellant's Petition and that another person would be making a decision on the Petition. Appellant recognizes that the merits of the Petition are outside the jurisdiction of the Board. Nonetheless, since the Examiner has extensively commented on the merits of the Petition in the Supplemental Examiner's Answer, Appellant feels compelled to address the Examiner's remarks for completeness. A copy of the Petition is attached hereto as Exhibit A (Exhibits thereto omitted).

Appellant replies to the Examiner's comments pertaining to Appellant's Petition in the order that the comments were presented in the Supplemental Examiner's Answer using the section/sub-section numbering scheme applied in the Petition.

A. Section II, sub-section A of the Petition.

In the Petition, Appellant submitted that the Examiner's rejection under 35 U.S.C. § 112, first paragraph, of the phrase "at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees" as recited in independent claim 144 constituted a new ground of rejection. This phrase was not previously rejected by the Examiner in the March 2004 Office Action. The Examiner states that "[a]s can be found in the final rejection as well as the examiner's answer, claims 29-300 were rejected under 35 U.S.C. 112 first paragraph as not being adequately supported in the specification. Claims 29-300 include claim 144. Therefore this is not a new rejection." (Supplemental Examiner's Answer, page 5, paragraph 1). Appellant respectfully submits that if a rejection of a claim is made without any supporting rationale whatsoever, then the rejection is *prima facie* incomplete. The Examiner did not provide any rationale to support the rejection of

claim 144 under 35 U.S.C. § 112, first paragraph until the Examiner's Answer. Appellant respectfully submits that the supplementation of the rejection of claim 144 under 35 U.S.C. § 112, first paragraph to provide a rationale to support the rejection in the Examiner's Answer constitutes a new ground of rejection which Appellant did not previously have a fair opportunity to address.

B. Section II, Sub-section B of the Petition.

In the Examiner's Answer, the Examiner replied to Appellant's remarks in the April 2005 Appeal Brief that Warren did not teach or suggest the subject matter of dependent claim 192. While replying, the Examiner incorporated for the first time the teachings of Duncan into the rejection that was once over Warren alone. (See Examiner's Answer, page 20, paragraph 3). In the Petition, Appellant submitted that the Examiner's combination of Duncan with Warren to reject claim 192 constitutes a new ground of rejection since the previous rejection of claim 192 under 35 U.S.C. § 103(a) on page 7 of the Examiner's Answer was in view of Warren alone.

In the Supplemental Examiner's Answer, the Examiner states that "[a]s can be clearly seen in the examiner's answer page 9 beginning on line 14, claim 192 is rejected over the references as applied to the claims above and further in view of Duncan, Chisholm et al. or Paravano." (Supplemental Examiner's Answer, page 5, paragraph 2). The phrase "over the references as applied to the claims above" referred to by the Examiner is in the rejection of dependent claim 192 under 35 U.S.C. § 103(a) that immediately follows the base rejection of the independent claim 176 under 35 U.S.C. § 103(a) as being unpatentable over Bays in view of Warren. Therefore Appellant submits that the Examiner's use of the phrase "over the references as applied to the claims above" refers to the base rejection of independent claim 176 under 35 U.S.C. § 103(a) as being unpatentable over Bays in view of Warren, not the base rejection of independent claim 176 under 35 U.S.C. § 103(a) as being unpatentable over Warren alone.

Moreover, the Examiner's rejection of independent claim 176 under 35 U.S.C. § 103(a) as being unpatentable over Warren alone already includes dependent claim 192 in the listing of claims under that particular rejection. Therefore It would be redundant for the phrase "over the references as applied to the claims above" in the Examiner's

rejection of claim 192 under 35 U.S.C. § 103(a) as being unpatentable further in view of Duncan, Chisholm or Paravano to refer to the rejection of independent claim 176 under 35 U.S.C. § 103(a) as being unpatentable over Warren alone.

The Examiner's Answer on page 20, paragraph 3 was in response to Appellant's remarks concerning the rejection of claim 192 under 35 U.S.C. § 103(a) as being unpatentable over Warren alone. In addressing Appellant's remarks, the Examiner incorporated the teachings of Duncan to further support the rejection, thus creating a new rejection of claim 192 under 35 U.S.C. § 103(a) as being unpatentable over Warren in view of Duncan. Since the rejection of claim 192 under 35 U.S.C. § 103(a) as being unpatentable over Warren in view of Duncan had not previously existed, Appellant submits that it constitutes a new ground of rejection.

C. Section II, Sub-section C of the Petition.

In the Petition, Appellant noted that in the Examiner's Answer the Examiner quoted the language from Form paragraph 7.31.02 "Rejection, 35 U.S.C. 112, 1st Paragraph, Enablement" while addressing Appellant's remarks with respect to the Examiner's new matter objection under 35 U.S.C. § 132. (See MPEP § 706.03(c); see also, MPEP § 2164.01 "Test of Enablement" (May 2004)). The March 2004 Office Action did not contain an objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph.

In the Supplemental Examiner's Answer, the Examiner states that "[t]he examiner was merely trying to make a point that the specification as originally filed does not appear to provide sufficient disclosure to enable any person skill in the art to know if one is to make the head/disc at an angle to the shaft or the angle is a result of the rivet being forced into tissue during use." (Supplemental Examiner's Answer, paragraph bridging pages 5 and 6 (emphasis added)). As set forth in the Examiner's Answer and repeated in the Supplemental Examiner's Answer, the Examiner contends that the specification is non-enabling. Yet the Examiner further contends that these remarks do not constitute a new objection to the specification as not meeting the enablement requirement under 35 U.S.C. § 112, first paragraph. (See Supplemental Examiner's Answer, paragraph bridging pages 5 and 6, "[t]here is no enablement rejection and therefore there is no new grounds of rejection"). Appellant respectfully submits that the

Examiner's remarks alleging that the specification is not enabling constitutes an objection to the specification as not meeting the enablement requirement under 35 U.S.C. § 112, first paragraph. The Examiner's objection concerning the lack of enablement did not appear until the Examiner's Answer. Accordingly, Appellant submits that the Examiner's objection to the specification as being non-enabling constitutes another new ground of rejection which Appellant did not have a fair opportunity to address.

IV. Conclusion.

For the foregoing reasons and the reasons set forth in the September 2005 Reply Brief and April 2005 Appeal Brief, Appellant submits that: (1) the amendment filed January 7, 2004 does not introduce new matter into the specification; (2) the specification supports the invention as now claimed; (3) the claims comply with the written description requirement under 35 U.S.C. § 112, first paragraph; (4) the claims are definite; (5) the Examiner's rejection under 35 U.S.C. § 103(a) in view of Warren has been overcome; (6) the Examiner's rejection under 35 U.S.C. § 103(a) in view of Bays and Warren has been overcome; (7) the Examiner's rejection under 35 U.S.C. § 103(a) in view of Bays and Warren, further in view of Duncan, Chisholm, or Paravano has been overcome; and (8) the Examiner's rejection under 35 U.S.C. § 103(a) in view of Bays, Warren, Duncan, Chisholm, or Paravano, further in view of Simons has been overcome.

Appellant submits that the claims are supported at least by the drawings. Further, Appellant submits that the Examiner's attempted redesign of the fastener of Warren and the repair tack of Bays extends beyond what either of the disclosures of Warren and Bays contemplated and would render the respective inventions inoperable for the intended purpose as taught in each of Warren and Bays. Accordingly, Appellant respectfully requests the Board to reverse all of the Examiner's objections and rejections stated in the Examiner's Answer.

If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: February 1, 2006

By: Todd M. Martin

Todd M. Martin

Registration No. 42,844

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Exhibit A

PATENT
 Attorney Docket No. 101.0023-04000
 Customer No. 22882
 Via U.S. Express Mail Label No. ER460924573US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Confirmation No. 3041
Gary Karlin Michelson, M.D.)	
Serial No.: 08/354,450)	Group Art Unit: 3764
Filed: December 12, 1994)	Examiner: D. DeMille
For: DEVICE FOR ARTHROSCOPIC)	
MENISCAL REPAIR)	

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Mail Stop Petitions
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

PETITION UNDER 37 C.F.R. § 1.181(a)

In response to the Examiner's Answer dated July 1, 2005 (the "Examiner's Answer"), Appellant petitions the Commissioner to send Appellant a corrected Examiner's Answer designating the following as new grounds of rejection: (1) the rejection of independent claim 144 under 35 U.S.C. § 112, first paragraph, as not being supported in the specification as originally filed relative to the phrase "at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees;" (2) the rejection of claim 192 under 35 U.S.C. § 103(a) over U.S. Patent No. 5,261,914 to Warren ("Warren") in view of U.S. Patent No. 4,648,202 to Duncan ("Duncan"); and (3) the objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph.

I. Background.

The above-identified application is on appeal from an Office Action dated March 19, 2004 (the "March 2004 Office Action"). Appellant filed an Appeal Brief on April 20, 2005 (the "Appeal Brief"). An Examiner's Answer was mailed July 1, 2005 (the "Examiner's Answer"). In the Examiner's Answer, the Examiner raised three new grounds of rejection.

In the March 2004 Office Action, a copy of which is attached hereto as Exhibit A, the Examiner rejected claims 29-300 under 35 U.S.C. § 112, first paragraph, as

Petition under 1.181(a) 9-1-05.doc

containing subject matter which was not adequately described as set forth in the objection to the specification under 35 U.S.C. § 112, first paragraph. For the objection to the specification under 35 U.S.C. § 112, first paragraph, the Examiner stated that "[t]here appears to be no support in the specification for the above noted language or the criticality why this is now being claimed." (March 2004 Office Action, page 3, paragraph 2). The "above noted language" referred to by the Examiner is contained in the objection to the Amendment filed January 7, 2004 under 35 U.S.C. § 132 as introducing new matter into the specification. The Examiner's new matter objection listed 12 phrases from the claims which the Examiner contended was new matter. (March 2004 Office Action, page 2, paragraph 1). Among the phrases objected to by the Examiner is the phrase "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees," as recited in dependent claim 145.

The Examiner rejected dependent claim 192, among other claims, under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,261,914 to Warren. Claim 192 recites the tissue rivet of independent claim 176 and dependent claim 187 having a plurality of projections positioned in a radially staggered configuration along the shaft of the tissue rivet. The Examiner's rejection did not provide any rationale specific to the subject matter of claim 192.

The March 2004 Office Action also did not contain any objection to the specification under 35 U.S.C. § 112, first paragraph, as not complying with the enablement requirement.

In the Appeal Brief, Appellant traversed the Examiner's new matter objection, objection to the specification under 35 U.S.C. § 112, first paragraph, and the claim rejection under 35 U.S.C. § 112, first paragraph, as they related to the phrase "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees," as recited in dependent claim 145. (Appeal Brief, pages 11-13, 16, and 17). A copy of the Appeal Brief is attached hereto as Exhibit B.

Appellant explained in the Appeal Brief that Warren did not teach or suggest the subject matter of claim 192, and that the Examiner did not provide any grounds and/or

motivation for the rejection specific to the subject matter of claim 192. (Appeal Brief, page 27).

In the Examiner's Answer, the Examiner maintained the objections and rejection to the phrase "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees," as recited in dependent claim 145. (Examiner's Answer, page 5, paragraph 1). A copy of the Examiner's Answer is attached hereto as Exhibit C. In addition to maintaining his positions, the Examiner stated "[t]he parent claim 144 recites the first portion of the flexible member forms an included angle greater than 90 degrees that likewise is not contingent on when the device is in use. Likewise this limitation is not supported by the disclosure as originally filed." (Examiner's Answer, page 5, paragraph 1). Appellant respectfully submits that the Examiner's further rejection of claim 144 constitutes a new ground of rejection.

The Examiner also stated that "[r]egarding Appellant's arguments in paragraph V subparagraph B9, Duncan teaches the plurality of projections in radially staggered configuration as claimed and would have been an obvious provision in Warren. There is no unobviousness to the exact shape of the projections as long as they prevent removal of the fastener." (Examiner's Answer, page 20, paragraph 3). Appellant respectfully submits that the Examiner's new combination of Warren in view of Duncan to reject claim 192 constitutes a new ground of rejection.

The Examiner further stated that "[t]he specification doesn't appear to provide such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." (Examiner's Answer, page 12, paragraph 2). Appellant respectfully submits that the Examiner's enablement rejection constitutes a new ground of rejection.

II. Arguments.

Appellant submits that the Examiner's Answer raised three new grounds of rejection. According to information posted by the Office in the Board of Patent Appeals and Interferences section of the United States Patent & Trademark Office website, the Appellant is permitted to seek the TC Director's supervisory review of the Examiner's Answer when the Appellant alleges that a rejection in an Examiner's Answer is a new

ground of rejection, but the Examiner did not designate the rejection as a new ground of rejection. (BPAI FAQ-Rules of Practice before the BPAI (effective 13SEP2004), Section F, question 5, accessible at www.uspto.gov/web/offices/dcom/bpai/fr2004/bpaifaq.html (August 26, 2005)). Additionally, "[i]f the TC Director or designee decides that the rejection is considered a new ground of rejection, the examiner would be required to send a corrected examiner's answer that identifies the rejection as a new ground of rejection in a separate examiner's answer and include the approval of the TC Director or designee." (BPAI FAQ-Rules of Practice before the BPAI (effective 13SEP2004), Section F, question 5 (August 26, 2005)).

- A. The new ground of rejection of independent claim 144 under 35 U.S.C. § 112, first paragraph as not being supported in the specification as originally filed relative to the phrase "at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees."

In the Examiner's Answer, the Examiner stated that the limitation in independent claim 144 where "the first portion of the flexible member forms an included angle greater than 90 degrees" is also "not supported by the disclosure as originally filed." (Examiner's Answer, page 5, paragraph 1). This phrase was not previously rejected by the Examiner in the March 2004 Office Action. Appellant respectfully submits that the Examiner's rejection under 35 U.S.C. § 112, first paragraph, of the phrase "at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees" as recited in independent claim 144 constitutes a new ground of rejection which requires the approval of the TC Director or designee as outlined by the procedure set forth in the "BPAI FAQ-Rules of Practice before the BPAI."

- B. The new ground of rejection of dependent claim 192 under 35 U.S.C. § 103(a) over Warren in view of Duncan.

In the Examiner's Answer, the Examiner replied to Appellant's remarks that Warren did not teach or suggest the subject matter of claim 192 by incorporating for the first time the teachings of Duncan into the rejection that was previously over Warren alone. (See Examiner's Answer, page 20, paragraph 3). Appellant respectfully submits that the Examiner's combination of Duncan with Warren to reject claim 192 constitutes

a second new ground of rejection which requires the approval of the TC Director or designee as outlined by the procedure set forth in the "BPAI FAQ-Rules of Practice before the BPAI."

C. The new ground of rejection concerning the objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph.

In the Examiner's Answer, while addressing Appellant's remarks with respect to the Examiner's new matter objection under 35 U.S.C. § 132, the Examiner stated that "[t]he specification doesn't appear to provide such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." (Examiner's Answer, page 12, paragraph 2). The language quoted by the Examiner corresponds to the language from Form paragraph 7.31.02 "Rejection, 35 U.S.C. 112, 1st Paragraph, Enablement." (MPEP § 706.03(c); see also, MPEP § 2164.01 "Test of Enablement" (May 2004)). The March 2004 Office Action did not contain an objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph. Accordingly, Appellant submits that the objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph, constitutes a third new ground of rejection which requires the approval of the TC Director or designee as outlined by the procedure set forth in the "BPAI FAQ-Rules of Practice before the BPAI."

Appellant respectfully submits that Appellant has not had a fair opportunity to address the Examiner's new rejections while being under a non-final condition for submitting a response. Designating each of the following: (1) the rejection of claim 144 under 35 U.S.C. § 112, first paragraph, as not being supported in the specification as originally filed relative to the phrase "at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees;" (2) the rejection of claim 192 under 35 U.S.C. § 103(a) over Warren in view of Duncan; and (3) the objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph, as new grounds of rejection will permit Appellant the opportunity to pursue one of the options listed under 37 C.F.R. § 41.39(b).

III. Conclusion.

In view of the above remarks, Applicant respectfully requests the Commissioner to send Appellant a corrected Examiner's Answer designating: (1) the rejection of independent claim 144 under 35 U.S.C. § 112, first paragraph, as not being supported in the specification as originally filed relative to the phrase "at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees;" (2) the rejection of claim 192 under 35 U.S.C. § 103(a) over Warren in view of Duncan; and (3) the objection to the specification as not meeting the enablement requirement of 35 U.S.C. § 112, first paragraph, as new grounds of rejection.

If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: September 1, 2005

By: Todd M. Martin

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